IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	Docket: 18668CIP1 SER
ALTMAN et al.	Confirmation No.: 6963
App. Serial No. 10/800,134	Group Art Unit: 1657
Filed: March 11, 2004	Examiner: Naff, David M.

For: IMMUNONEUTRAL SILK-FIBER-BASED MEDICAL DEVICES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

I, Gregory H. Altman, Ph.D. declare as follows:

1. I am a co-inventor named in the above-identified patent application.

2. I received a Bachelor of Science in Chemistry and a Ph.D. in Biotechnology Engineering from Tufts University, Boston. I have done extensive research on and am the author or coauthor of numerous publications in the areas of silk and medical devices, including silk medical devices and implantable knitted silk fabrics and devices. A list of my publications is attached hereto as Exhibit A. Since 2010 I have been Vice President and General Manager of Allergan Medical, a division of the owner on this patent application. I was formerly President and Chief Executive Officer of Serica Technologies, Inc. from 1998 to 2010. Prior to Serica Technologies, Inc., I was a Research Assistant Professor in the Department of Biomedical Engineering at Tufts University and a Research Assistant Professor in the Department of Orthopaedic Surgery at Tufts University School of Medicine. I have been involved in research and industry in the field of medical devices for at least fourteen years.

3. Based upon my experience and training I am an expert in the field of silk medical devices including in the field of implantable knitted silk fabrics.

4. I have been advised that the Examiner of this application has cited U.S. Patent No. 7,285,637 ("Armato") and that the Examiner has also relied upon U.S. Patent No. 6,303,136 ("Li") and U.S. Patent No. 5,736,399 ("Takezawa"). I have reviewed and understand these three references.

5. The claimed invention is an implantable knitted fabric comprising one or more individual yarns, the yarn comprising one or more sericin-extracted silk fibroin fibers that retain their native protein structure and have not been dissolved and reconstituted, the fibers being biocompatible and non-randomly organized, wherein the yarn promotes ingrowth of cells around said fibroin fibers and is biodegradable.

6. In my opinion, a person of ordinary skill in the art would not consider the claimed invention in this patent application to be obvious based upon Armato or Armato in combination with either of the two other cited references. I base this opinion on the facts set forth below which show that:

(1) Armato is directed to a process for producing non-woven silk fiber fabrics, as stated in the title and abstract of Armato;

(2) Figures 1A and 1B of Armato are scanning electron microscopy (SEM) pictures of non-woven fabrics;

(3) Non-woven fabrics (Armato) are different from knitted fabrics both in terms of the structural construction of the fabrics and the configuration of the fibers, and;

(4) Armato's fibers are randomly organized whereas the fibers of our invention are non-randomly organized.

7. I understand that the Examiner relies upon the statement in Armato that "[t]he use of textile methods would theoretically be possible to weave using merely degummed silk fibroin fibers." However, woven fabrics are notably distinct from our claimed knitted fabric. It is well known that in woven fabrics, yarns are at right angles as opposed to being formed by the process of inter-looping, and as a result the properties of the woven and knitted fabrics are quite different. Additionally, Li also teaches that the matrix is "woven" into a mesh (see abstract of Li). Furthermore, the Takezawa reference teaches a device comprising "the woven body thereof" in column 2, line 25. Significantly, there is no mention or suggestion of a knitted fabric in any of Armato , Li and Takezawa.

8. In further clear distinction to each of Armato, Li and Takezawa:
(a) the claimed implantable fabric is "knitted" and therefore cannot by made by "weaving", and;
(b) the claimed implantable knitted fabric is not and cannot be a "non-woven" fabric.

9. It is important to understand that weaved, non-woven and knitted fabrics are three distinct types of fabrics. Furthermore, one such type of fabric does not teach or suggest the suitability of the other for a given application. Thus, the first two types of textile fabrics in Armato do not teach the third type of fabric which is our claimed invention, namely a knitted, implantable fabric because Armato specifically states in column 2, lines 32-33 that "[t]he aim of the present invention is to provide a method for the preparation of silk fibroin non-woven fabrics...".

10. These contrary teachings and distinctions between these three different types of fabrics are well known in the art. For example, on page 139 (attached) of Applied Basic Textiles by George E. Linton, Ph.D. First Edition, Duell, Sloan and Pearce, New York (1966), there is set forth eight types of textile fabrics. The following types of textile fabrics are each listed as a recognizably distinct fabric types: woven, knitted and nonwoven. "Woven" is described as "[y]arns interlace at right angles; warp is vertical; filling is horizontal"; "Knitted" is described as "[o]ne system of yarn inter-looping: a loop within a loop. "Nonwoven" is described as "[w]eb or sheet of textile-type fibers bonded together by application of narrow stripes or patterns of adhesive material or by bonding of fibers through chemical activation of the surface or by heat if thermoplastic fibers are used. Yarn is not used in this fabric."

11. Furthermore, on page 111 (attached) of Applied Basic Textiles by George E. Linton, Ph.D. First Edition (1966), it is stated that "The American Society for Testing Materials, Philadelphia, Pennsylvania, defines a nonwoven fabric as a 'textile structure produced by bonding and/or interlocking of fibers, accomplished by mechanical, chemical, thermal, or solvent means and combinations thereof. The term does not include paper or fabric which are woven, knitted, tufted, or those made by wool and other felting processes.'"

12. Additionally, on page 117 (attached) of Applied Basic Textiles by George E. Linton, Ph.D. First Edition (1966), it is stated that "There is no system of yarn or thread used to make nonwoven fabrics; they have no warp and no filling as in woven fabrics, or loops as in knitted materials."

13. Armato clearly teaches only a process for producing "non-woven" silk fiber fabrics which is contrary to the teachings of our claimed invention and indeed teaches away from it because Armato specifically states in column 5, lines 58-62 that "It can be clearly noted in SEM photographs that voids are distributed randomly and can be controlled by the concentration of silk fibroin or by preparing multiple layers of silk fibroin fiber structures." In contrast, our knitted implantable fabric is comprised of non-randomly organized fibers as set forth in our claims. And as stated Li discloses that the matrix is "woven" into a mesh (see abstract of Li) and Takezawa discloses a device comprising "the woven body thereof" (column 2, line 25).

14. Furthermore, it is clear that the fibers in Armato have been dissolved and reconstituted as shown in the Examples of Armato (see column 4, lines 50-52 of Armato). Armato states that "[a]s can also be seen from the data of Table 1, the process in accordance with the present invention allows the silk fibroin to be dissolved." Not only does Armato explicitly use the term "dissolve" but Armato also sets forth solubility data in the tables in addition to listing the final resulting fabric forms as "nonwoven fabrics". Thus, the teachings of Armato are contrary to our claimed invention and cannot be remedied by what is disclosed in Li or Takezawa. As stated paragraph [0021] of our patent application and as presently claimed as our invention, the yarn comprises one or more sericin-extracted silk fibroin fibers that retain their native protein structure and have not been dissolved and reconstituted.

15. Therefore, for the reasons stated above, I do not agree with the position taken in the Office Action that it would have been obvious to one of ordinary skill in the art at the time

the invention was made to have arrived at the present invention in view of the a combination of the teachings of Armato, Li and Takezawa.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent that issues therefrom.

Date: 5·1 , 2012

Gregory H. Altman, Ph. D.

Exhibit A

PUBLICATIONS (* corresponding author)

R. L. Horan, D. Bramono, J.R.L. Stanley, Q. Simmons, G. H. **Altman**. 2009. Biological and biomechanical assessment of a long-term bioresorbable silk-derived surgical mesh in an abdominal body wall defect model. Hernia. 13 (2): 189-99.

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Several pending

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